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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/390,851 09/07/99 PEDERSEN

H 5655.204-US

EXAMINER

HM12/0328

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ART UNIT

PAPER NUMBER

1627

DATE MAILED:

03/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/390,851	Applicant(s) PEDERSEN ET AL.	
	Examiner Barba M. Koroma	Art Unit 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2000.
- 2a) ☐ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

**DETAILED OFFICE ACTION**

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, Ph.D., Supervisory Patent Examiner at [jyothsna.venkat@uspto.gov](mailto:jyothsna.venkat@uspto.gov) or 703-308-2439. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

**Restriction/Election**

2. Claims 1-27 are pending in this application.
3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to a method for in vitro selection from a library of catalyst molecules, classified in class 435, subclass 7.4.
  - II. Claim 8-11 drawn to a library of polypeptides, classified in class, 500, subclass... 300+.
  - III. Claims 12-15, drawn to a library of catalyst molecules, classified in class 435, subclass 69.1.

- IV. Claims 16-17, drawn to a library comprising natural polymers, natural and unnatural polymers molecules, or unnatural polymers molecules, or small organic and inorganic compounds, classified in class 500, subclass 300+.
  - V. Claim 18, drawn to a method of in vitro selection where the catalyst molecules and substrate capable of being catalyzed into a product are of different chemical substance, classified in class, 435 subclass, 69.2 .
  - VI. Claim 19-21, drawn to a method for in vitro selection where the catalyst is coupled to an affinity tag, classified in class 435, subclass 7.1.
  - VII. Claim 22-24, drawn to a method for in vitro selection where the selecting for catalyst molecules of interest is done by immobilization, classified in class 436, subclass 174.
  - VIII. Claim 25-26, drawn to a method for in vitro selection, wherein the isolation of an entity allows the unambiguous identification of the catalyst molecules of interest, class 435, subclass 4.
  - IX. Claim 27, drawn to a method for producing a catalyst molecule of interest, classified in class 435, subclass, 69.1.
4. The inventions listed above are deemed patentably distinct and appropriate for restriction as shown, because they are of divergent subject matter, have acquired a separate status in the art, and have separately burdensome manual and/or computer-aided bibliographical searches. The inventions are distinct, each from the other because:

5. Inventions belonging to groups I, V, VI, VII, and VIII are related as patentably distinct **methods or procedures of using**. The inventions that fall in this category are distinguishable as follows:

Group I is a method of in vitro selection of a catalyst molecule of interest where any catalyst molecule of interest may be used. The only defining feature being that the catalyst molecule of interest *allows multiple catalytic turnovers and is provided in the form of individual units*.

Group V is a method of in vitro selection of a catalyst molecule of interest where the catalyst and substrate must belong to different sets of chemical substances.

Group VI is a method of in vitro selection of a catalyst molecule of interest where the catalyst molecules of interest must be coupled to affinity tags.

Group VII is a method of in vitro selection of a catalyst molecule of interest where the electing for a catalyst molecule of interest is done by *specific immobilization to said product molecule*.

Group VIII is a method of in vitro selection of a catalyst molecule of interest where the isolation of a catalyst molecule of interest is based on the presence of an entity which *allows unambiguous identification of the said catalyst molecule of interest either by physical or chemical procedures*.

6. Groups II, III and IV are patentably distinct **compositions or libraries**. The inventions that fall in this category are distinguishable from each other as follows:

Group II is a method of in vitro selection of a catalyst molecule of interest where the library of molecules from which the said catalyst selected is limited to polypeptides

Group III is a method of in vitro selection of a catalyst molecule of interest where the library of molecules from which the said catalyst selected is limited to natural or unnatural nucleic acids.

Group IV is a method of in vitro selection of a catalyst molecule of interest where the library of molecules from which the said catalyst selected is limited to natural polymers, unnatural polymer molecules, small organic molecules, or a mixture of said molecules.

7. Group IX is a patentably distinct **method of making or producing** an isolated catalyst molecule of interest in a suitable quantity.

8. An invention which is a **composition or library** is distinguishable from an invention which is **method or procedure of using**. Both categories of inventions are also patentably distinguishable from an invention that is a **method of making or producing**. This is because these broad categories of inventions are predicated upon different experimental objectives, are capable of utilizing different reagents and reactants, and result in different outcomes. Thus, art that anticipates or renders obvious one group does not anticipate or render obvious another.

### *Election of Species*

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the recitations of claims 1, 25, and 26 are generic.

Applicant is requested to elect a single species from each claim in the groups as listed:

Group I:

Claim 1: elect a specific type of catalyst molecule of interest such as peptides, nucleic acids, or small organic compounds.

Group IX

Claim 26: elect a specific method of production such E. coli transfection or transgenic animal production.

10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


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12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. All inquiries pertaining to this case should be directed to *Barba M. Koroma*. This examiner can normally be reached at: 703 305 1915, at *9:00am to 5:00pm, Monday through Friday*.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, PhD, can be reached at: 703 308 2439. The phone number for the organization where this application or proceeding is assigned is: 703 308 2742. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is: 703 308 1235.

Barba M. Koroma, Ph.D  
Patent Examiner  
AU 1627

  
DR. JYOTHSNA VENKAT PH.D  
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